

Message Text

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22

ORIGIN HEW-06

INFO OCT-01 ARA-10 EA-09 ISO-00 OES-06 COME-00 EB-07 MED-03

/042 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK;

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EA/PHL:RWILLNER (INFO)

----- 059631

R 311543Z AUG 76

FM SECSTATE WASHDC

TO AMEMBASSY MANILA

AMEMBASSY MANAGUA

UNCLAS STATE 215588

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, RP, NU

SUBJECT: RECALL OF DRUG DUE TO LABEL MIX-UP D-454-6

1. FDA ADVISES OF THE FOLLOWING DRUG RECALL:

PRODUCT INVOLVED: "QUINAGLUTE' DURA-TABS 324 MG. (5 GR)
100 TABLETS/BOTTLE, ORAL ROUTE OF ADMINISTRATION, RX DRUG.
PRODUCT PACKED IN SHIPPING CASE OF 12 CARTONS, EACH CARTON
CONTAINS 12 BOTTLES. OUTER SHIPPING CASE MARKED "QUINA-
GLUTE TABS R 60978 12 X 12 X 100". INNER CARTONS LABELED
WITH BOTTLE LABEL AND STAMPED 12 X 100 IN TWO CORNERS.

PRODUCT IDENTIFICATION: QUINAGLUTE DURA TABLETS (WHITE
COMPRESSED UNCOATED TABLETS) WITH THE FOLLOWING LOGOS (ONE
SIDE OF TABLET HAS A LETTER C INSIDE AN ERLLENMEYER FLASK,
WHILE THE OTHER SIDE OF THE TABLET HAS THE FACE OF A CLOCK).
PRODUCT IS PACKED IN AMBER GLASS BOTTLES WITH WHITE CHILD
RESISTANT CAP. ONLY LOT R 60978 EXPIRATION DATE 1981 IS
UNDER RECALL. PRODUCT IS LABELED WITH ORANGE AND TANNISH
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BROWN LABEL THAT IS LABELED IN PART "XXX NDC 0041-0101-10

QUINAGLUTE (QUINIDINE GLUCONATE) DURA TABS EACH TABLET
CONTAINS QUINIDINE GLUCONATE 324 MG. (5 GR.) 100 TABLETS XXX
COOPER LABORATORIES, INC., WAYNE, N.J. 07470 XXX". PRODUCT
IS INDICATED FOR PREVENTION OF PREMATURE ATRIAL, NODAL OR

VENTRICULAR TACHYCARDIA, ATRIAL FLUTTER AND FIBRILLATION.

MANUFACTURERS: COOPER LABORATORIES
SAN GERMAIN, PUERTO RICO

RECALLING FIRM: COOPER LABORATORIES, INC.
FAIRFIELD ROAD
WAYNE, NEW JERSEY 07470

2. REASON FOR RECALL: ON OR ABOUT 7/7/76 COOPER LAB-
ORATORIES WAS NOTIFIED THAT YELLOW TABLETS WERE FOUND IN
A BOTTLE LABELED QUINAGLUTE DURA TABLETS. QUINAGLUTE
TABLETS ARE WHITE IN COLOR. COOPER ASSAYED THE YELLOW
TABLETS AND IDENTIFIED THE TABLETS AS (AMINOPHYLLINE)
AMINODUR DURA TABLETS 300 MG. PER TABLET. ON 7/30/76 THE
FIRM SENT MAILGRAMS TO ALL ACCOUNTS INFORMING THEM OF THE
PROBLEM.

ON OR ABOUT 8/7/76 THE FIRM SENT LETTERS TO ALL PHARMACIES
HOSPITALS, NURSING HOMES, PHYSICIANS AND ALL DIRECT
ACCOUNTS THAT THEY RETURN ALL STOCK OF THE LOT INVOLVED
AND CONTACT ANY PATIENTS THROUGH PHYSICIANS OR PHARMACISTS
WHO MAY HAVE RECEIVED THE PRODUCT BETWEEN 3/25/76 AND DATE
OF RECEIPT OF THE LETTER. THE FIRM HAS USED 3/25/76 AS
A PRECAUTION TO INSURE THAT THE DISTRIBUTION OF THE
INVOLVED LOT IS COVERED.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL LETTER REGARDING
THE AFFECTED LOT OF QUINAGLUTE DURA TABLETS. ANY QUES-
TIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:
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COOPER LABORATORIES
MANILA, PHILIPPINES

FARQUI MED
APARTADO 669
505 MANAGUA, NICARAGUA

EACH FIRM HAD ONLY ONE BOTTLE. ROBINSON

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 31 AUG 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE215588
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK;
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760331-0323
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t1976082/aaaaabdf.tel
Line Count: 116
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: cahillha
Review Comment: n/a
Review Content Flags:
Review Date: 22 MAR 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <22 MAR 2004 by ReddocGW>; APPROVED <02 NOV 2004 by cahillha>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF DRUG DUE TO LABEL MIX-UP D-454-6
TAGS: OGEN, ETRD, EIND, TBIO, RP, NU, FDA
To: MANILA MANAGUA
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006